IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON

In RE: SERZONE

PRODUCTS LIABILITY LITIGATION

MDL NO. 1477
Hon. Joseph R. Goodwin

Appeal of Willard Daniels (Docket No. 523)

MEMORANDUM OPINION AND ORDER

By virtue of the Third Amended Settlement Agreement ("Agreement") (Docket Sheet Document # 184), the parties designated the undersigned to review any appeals filed by plaintiffs regarding decisions by the Claims Administrator placing them in certain fund categories pursuant to the Agreement and the Schedule of Payments, which is attached to the Agreement as Exhibit B. The Schedule of Payments describes the objective criteria needed to qualify for recovery under Funds A, B, C and D. Funds A, B and C require a showing of a qualifying medical condition and submission of documents showing that the qualifying medical condition is temporally associated with the use of Serzone®. Funds A, B and C are subcategorized according to specific medical criteria. Fund D is the sole fund category which requires only that the plaintiff "can document that he or she purchased Serzone® or used Serzone®, or alleges that he or she was injured by Serzone® and is not making

a claim for benefits or eligible under Funds A, B or C ...." (# 184, Exhibit B.)

Procedural History and Submission of Records

On May 12, 2005 (received May 16, 2005), Lorene O'Grady ("Plaintiff"), as Personal Representative of the Estate of Willard Daniels ("Daniels"), through counsel, submitted an Inventory Form alleging that Daniels suffered "acute liver failure arising from acute hepatocellular injury, resulting in death on April 17, 2002."

On February 3, 2006, Plaintiff submitted a claim form seeking placement and award within Fund A-1, alleging that Daniels "died from Acute Liver Failure arising from Acute Hepatocellular Injury." "Acute Liver Failure" as used in Fund A, "requires the following within twelve (12) weeks after last documented use of Serzone®: (1) development of hepatic encephalopathy; or (2) the diagnosis of fulminant liver failure and an elevated prothrombin time with an international normalized ration (INR) > 1.5." "Acute Hepatocellular Injury, as used in Fund A, requires evidence of acute hepatocellular damage documented in a pathology report."

By letter dated February 8, 2006, the Claims Administrator notified counsel for Plaintiff that the claim was incomplete, in that hospital records, medical records and laboratory reports for Daniels for the five (5) years immediately preceding the qualifying Fund A injury to the present were not submitted with the Claim Form. Counsel for Plaintiff responded that "we did in fact submit

all records in our possession, and which we could obtain from May 20, 1997 up to Mr. Daniels' time of death in April 2002." Counsel listed the records produced. The most recent records listed by counsel are dated April 5, 2002; however, Mr. Daniels died on April 17, 2002. It appears that he was in Borgess Medical Center continuously from April 3, 2002, until his death two weeks later. Thus the Claims Administrator lacked the complete records of Daniels's final hospitalization.

The Serzone® National Class Settlement Claims Manual ("Claims Manual"), at page 23, regarding Fund A claims, sets forth the obligations of the Claimant and the Claims Administrator:

> The Claims Administrator must ensure that each Claimant has provided all responses which are necessary to properly evaluate the Claim - including those that may only impact the benefit reductions and enhancements. In the event a Claimant fails to provide any material information, the Claims Administrator should advise the Claimant of the deficiency and request the Claimant to provide the necessary information. In the event the Claimant fails to correct the deficiency, the Claims Administrator will, to the extent it is able, presume that the missing information would not support the claim and make an appropriate benefit determination. Example 1) If a Claimant denies a preexisting medical condition, but fails to provide the appropriate medical records or medical authorizations necessary to confirm this fact, then the Claims Administrator will evaluate the claim using the "Fund A Matrix for Claimants with Chronic Liver Conditions." * * *

On May 23, 2006, the Claims Administrator advised that Daniels had been placed in Fund B-III with no pre-existing liver condition, thus entitling Plaintiff to a payment of $25,000.

> Claimants who developed, and have a contemporaneous diagnosis of, one or more of the qualifying conditions listed below, the management or treatment of which required hospitalization or at least three (3) independent instances of outpatient care for the treatment of the underlying qualifying condition may recover under matrix level B-III.

(Ex. B, Schedule of Payments.) The qualifying conditions are jaundice and elevations of liver enzymes and total bilirubin.

On June 26, 2006, Plaintiff, by counsel, appealed the decision of the Claims Administrator, attaching numerous medical records of Mr. Daniels. (# 523.) On August 7, 2006, Bristol-Myers Squibb Company ("BMS") filed a brief in response to the appeal, also attaching numerous medical records of Mr. Daniels. (# 758.)

BMS did not file an appeal in its own right, although it had the right to do so within thirty (30) calendar days of the Claims Administrator's decision. (Third Amended Settlement Agreement, ¶ 7.9, at 14.) Accordingly, any complaints which BMS has of the Claims Administrator's decision will not be heard.

The court has carefully considered the submissions of both parties.

Standard of Review

Under the Agreement, the undersigned must "review ... all documents submitted to the Claims Administrator (including the completed Claims Form and supporting documentation as well as any documents submitted by BMS) ...." (# 184, p. 14.) Pursuant to the Memorandum Opinion and Order Approving Settlement and Certifying

the Settlement Class (# 296) entered by the presiding Multi-District Litigation ("MDL") Judge, the Hon. Joseph R. Goodwin, the undersigned must set aside the Claims Administrator's award if the factual determination was "clear error." (# 296, p. 49.)

"Clear error" has not been defined by the parties or the court. Pursuant to Rule 72(a) of the Federal Rules of Civil Procedure, which governs the review of a magistrate judge's order on a nondispositive matter, a decision shall not be modified or set aside unless it is "clearly erroneous or contrary to law." In Marks v. Global Mortgage Group, Inc., 218 F.R.D. 492, 495 (S.D. W. Va. 2003), Judge Goodwin observed that "[a] district court should reverse a magistrate judge's decision in a discovery dispute as 'clearly erroneous' only if the district court is left with a definite and firm conviction that a mistake has been made." (Citing Clark v. Milam, 155 F.R.D. 546, 547 (S.D. W. Va. 1994)). In the criminal realm, "plain error" as used in Rule 52(b) of the Federal Rules of Criminal Procedure is defined as affecting "substantial rights." In United States v. Olano, 507 U.S. 725, 733-34 (1993), the United States Supreme Court explained that there must be an error that is "plain," which affects "substantial rights." For an error to affect substantial rights, it must "have affected the outcome of the district court proceedings." Id. at 734. If these conditions are met, the court may exercise its discretion to notice the error, but only if the error "'seriously

affect[s] the fairness, integrity or public reputation of judicial proceedings.'" Id. at 736 (quoting United States v. Atkinson, 297 U.S. 157, 160 (1936)).

Contentions of the Parties

Plaintiff contends that "Mr. Daniels suffered from acute hepatocellular injury in temporal relation to his ingestion of Serzone® and the fact that he eventually died from the injury." (# 523, at 1.) Plaintiff relies on the 2006 report of Dr. Kevin Herzog, the records from Borgess Medical Center indicating liver failure and an elevated PT/INR [prothrombin time and international normalized ratio] in April, 2002, and Dr. Herzog's pathology report of a liver biopsy, dated February 1, 2002. Id., at 1-2. According to Plaintiff, Daniels' last use of Serzone® was February 1, 2002. Id., at 3. Plaintiff denies that Daniels suffered "from any other chronic liver diseases." Id., at 4.

BMS argues that Plaintiff "failed to provide any pathology report which documents acute hepatocellular injury." (# 758, at 1.) BMS further asserts that Daniels suffered from chronic liver disease, prior to and during his Serzone® use, and must be considered as a Fund B Claimant subject to the matrix for re-existing chronic liver conditions. Id., at 2. In other words, BMS argues that the Claims Administrator was correct in refusing Fund A eligibility, but in error in finding no pre-existing chronic

liver condition. As noted above, this latter argument will not be heard.

Pathology Report

On February 1, 2002, Plaintiff underwent a percutaneous aspiration liver biopsy. Board-certified pathologist Kevin M. Herzog, M.D.'s final diagnoses were "chronic active hepatitis with moderate activity (Grade 3 of 4), bridging fibrosis with probable early cirrhosis (stage 4 of 4)." Dr. Herzog reported:

> The histologic findings are nonspecific with regard to etiology, but the degree of inflammatory activity and plasma cell content suggest an autoimmune basis. Correlation with serologic and clinical findings is essential.
>
> Microscopic Examination:
> Multiple tissue levels of this adequate liver biopsy demonstrate a marked degree of portal-portal fibrosis, which in one instance appears [to?] surround a hepatocyte aggregate to for a regenerative nodule. Within the fibrous septa is a brisk lymphoplasmacytic inflammatory infiltrate. There is readily identifiable piecemeal necrosis and spotty necrosis within nonportal areas. Ballooning degeneration of hepatocytes and apoptotic necrosis are identified in these areas. Occasional eosinophils are seen, but there is no neutrophilic component to the inflammatory infiltrate. No granulomas are identified. Interlobular bile ducts appear normal in quantity and morphology, but there is modest cholangiolar proliferation within portal septa. There is no histologic evidence of cholestasis. No hepatocellular inclusions are identified. There is no abnormality of the vasculature or sinusoids. There is no evidence of neoplasm. * * * A reticulin stain confirms the presence of widespread reticulin fibrosis and highlights the altered reticulin framework suggestive of early cirrhosis present in the biopsy. A Masson trichrome stain further confirms the presence of bridging fibrosis and probably early cirrhosis.

By letter dated January 30, 2006, to Claimant's counsel, Dr. Herzog wrote:

> Based upon review of the medical records provided, Mr. Willard C. Daniels was first diagnosed with a liver disorder (11/1/01) after having initiated treatment with nefazodone (Serzone®) (11/97). A biopsy performed on 2/1/02 and interpreted by me showed ongoing acute hepatocellular injury as well as evidence that the process had probably been extant for at least six months (hence the term "chronic"). The duration of the disorder cannot be more precisely determined. No definite etiology for the disorder was apparent after microscopic examination and an extensive battery of laboratory tests.

BMS claims that Dr. Herzog's 2006 letter is not a "pathology report," is inconsistent with the findings made in 2002, and does not obviate the requirement for presenting a liver biopsy or other pathology report. (# 758, at 6-8.)

The Claims Manual lists the required documents for Fund A, including:

> Medical report or hospital records documenting a hospital admission in which treatment was provided for the alleged Serzone® -related acute liver failure. The subject report and/or qualifying records must have been prepared by a hepatologist or board certified gastroenterologist or, in the case of death, a board certified pathologist and must include a diagnosis, within twelve (12) weeks of claimant's last use of Serzone® , of the development of hepatic encephalopathy or fulminant liver failure with an elevated prothrombin time and international normalized ratio (INR) greater than 1.5 that resulted in death, liver transplant or placement on the UNOS liver transplant list.

The court finds that Dr. Herzog's 2006 letter does not establish Willard Daniels' Fund A eligibility for the following reasons: Dr. Herzog's diagnosis is not contemporaneously reflected

in hospital records in which treatment for the alleged Serzone® related liver failure was provided by a treating or consulting hepatologist or board certified gastroenterologist. As the court noted above, counsel for Plaintiff did not submit the complete hospital records, despite being notified of the deficiency. Moreover, Dr. Herzog's letter does not state that Mr. Daniels' medical records support his diagnosis of acute hepatocellular injury. The court has reached this conclusion in reliance on the Claims Manual, section 2.(5) Fund A - Initial Injury Classification and Assessment, found at page 26. The court has also relied upon the Claims Manual's mandate that if medical records are not submitted, then the Claims Administrator must presume that the missing information would not support the claim. Accordingly, the court finds that the Claims Administrator did not commit clear error when it placed Willard Daniels in Fund B.

Even if the court were to accept Dr. Herzog's 2006 letter as a pathology report relating back to 2002, Plaintiff would still not qualify for Fund A status. This is because Plaintiff has failed to provide hospital records or a doctor's report that confirm that Daniels had "hepatic encephalopathy" or "fulminant liver failure." It is simply insufficient to allege that he had "acute hepatocellular injury."

Turning to the placement of Plaintiff's claim in Fund B-III, the court finds that the decision of the Claims Administrator was not clear error.

Plaintiff does not qualify for placement in Fund B-I or B-II. For Fund B, Plaintiff must show, in addition to an acute liver injury, that Daniels developed significant simultaneous elevations of liver enzymes and total bilirubin levels, that is:

> (1) AST and/or ALT levels of greater than or equal to 15 times the Plaintiff's average elevated enzyme level prior to the initial use of Serzone® simultaneous with total bilirubin levels greater than or equal to two times the Plaintiff's average elevated total bilirubin levels prior to the initial use of Serzone® or 2 mg/dl, whichever is greater, documented by two consecutive blood tests separated by at least two days but less than ninety days; or
> (2) One blood test establishing the requisite simultaneous elevations of AST and/or ALT and total bilirubin levels and a contemporaneous abnormal liver biopsy demonstrating evidence of acute hepatocellular injury.
>
> For Fund B-II, Plaintiff must show that Daniels had:
>
> (1) AST and/or ALT levels of greater than or equal to 10 times the Plaintiff's average elevated enzyme level prior to the initial use of Serzone® simultaneous or total bilirubin levels greater than or equal to three times the Plaintiff's average elevated total bilirubin levels prior to the initial use of Serzone® or 3 mg/dl, whichever is greater, documented by two consecutive blood tests separated by at least two days but less than ninety days.

Daniels' blood tests in the records provided to the Claims Administrator and the court do not reach the required levels for B-I or B-II.

Accordingly, it is hereby **ORDERED** that Plaintiff's appeal is **DENIED** because the decision of the Claims Administrator placing Plaintiff in Fund B-III was not clear error.

The Clerk is directed to transmit a copy of this Memorandum Opinion and Order to counsel for Ms. O'Grady, liaison counsel for plaintiffs and Bristol-Myers Squibb Company, and the Claims Administrator.

ENTER: August 10, 2006

Mary E. Stanley
Mary E. Stanley
United States Magistrate Judge